REMARKS

Claims 1-25, 27-39, 67-70 and 72-80 are currently pending in the above-identified application. The Examiner has indicated that claims 31-39 contain allowable subject matter. The Examiner has also indicated that claims 14, 21 and 24 would be allowable if rewritten in independent form. Claims 26, 40-66, and 71 were previously withdrawn. Examination and reconsideration of all pending claims are respectfully requested.

Claim Rejections under 35 U.S.C. §102

Claims 1-13, 15-20, 22-23, 25, 27-30, 67-70, 72-74, 786-78 and 80 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Ressemann et al. Such rejections are overcome as follows.

Claim 1 recites an assembly for crossing occlusive or stenotic material. The assembly comprises a guidewire comprising an axial passage. A drive shaft is rotatably and translatably extending through the axial passage of the guidewire. The drive shaft comprises a distal tip that can be rotated and advanced to create a path through the occlusive or stenotic material. Such an assembly is not described or suggested by the cited art.

The Examiner stated in the Final Office Action that Ressemann et al. describes such an assembly. Applicants disagree with the Examiner for at least two reasons.

First, it is well settled that even if the prior art device performs all the functions recited in the claim, the prior art cannot anticipate the claim if there is any structural difference. *See* MPEP § 2114. The claims require that the drive shaft is rotatably and translatably extending through the axial passage of the guidewire. Ressemann et al. explicitly states throughout the specification that the guidewire 42 is disposed through the drive shaft 92. *See* col. 9, lines 8-9, col. 6, lines 50-53, col. 6, lines 64-66. Moreover, Ressemann et al. does not appear to describe or suggest advancing the distal tip of the drive shaft to create a path through the occlusive or stenotic material. Instead, it appears that retraction of guidewire 42 causes expandable member 16 to expand. The description in Ressemann et al. does not provide the structure that is required

by the claims (i.e. drive shaft extending in the axial passage of the guidewire and/or a drive shaft that is rotated and advanced to create a path). For such reasons alone, independent claim 1 is allowable over Ressemann et al.

Second, claims must only be interpreted as broadly as their terms reasonably allow and it is well settled that words of a claim must be given their plain meaning. The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359 (Fed. Cir. 1999). *See also* MPEP § 2111.01.

A key issue in the present rejection is the Examiner's interpretation of the claim element "guidewire." To support his rejection of the pending claims, the Examiner stated in the "Response to Arguments" section of the Office Action:

> [T]he Rossemann et al' (sic) device do disclose the configuration in which a drive shaft (92) extends through the axial passage of the **guidewire (90)** and the drive shaft movably disposed within the guidewire (figs 1, 10 and col. 11, lines 41-45 and lines 51-54). (emphasis added)

The intrinsic evidence in both Ressemann et al. specification and Applicants' specification illustrate how the term "guidewire" is used by those of ordinary skill in the art, and go against the Examiner's unduly broad interpretation of the term "guidewire." A closer look at the referenced figures and passages show that Ressemann et al. does not describe or suggest the structure of the claims. In particular, Figures 1 and 10 illustrated that guidewire 42 is disposed within the drive shaft 92. *See also* Figures 4 and 5 which clearly illustrate that guidewire 42 is disposed within the drive shaft 92. Column 11, lines 41-45 and 51-54 merely describes the catheter sheath 90 and its relationship with the drive shaft.

Catheter sheath 90, which the Examiner equates to a "guidewire", is described as being "of a well known construction and can be made from polyethylene, KYNAR, a fluoropolymer and the like." The catheter sheath is in communication with port 82 so as to insure delivery of the fluids for infusion or aspiration. (*See* col. 11, lines 38-42). A person of ordinary skill in the art would not consider such a catheter sheath as a guidewire. It should be

noted that Ressemann et al. describes in great detail how the guidewire 42 is a different structure from the catheter sheath 90. *Compare* col. 7, lines 1-36 to col. 11, lines 41-46.

As is stated in U.S. Patent 6,059,767, which was incorporated by reference into the Applicants' present application, a conventional guidewire is generally used to "provide columnar strength to the catheter and is therefore used to guide and position conventional prior art catheters at target tissue sites." (*See the '767 patent* at col. 5, lines 10-14). Such a description of "guidewires" and "conventional catheters" is consistent with the methodology of what Ressemann et al. describes in its specification. In particular, Ressemann et al. describes its method as follows:

> Thus, the removal device 10 is of an over the wire construction which can facilitate removing the device 10 from, and replacing the device 10 in the patient because the guidewire 42 can remain within the patient." (Col. 6, line 67 to col. 7, line 3).
>
> The guidewire 42 is inserted intravascularly into the patient and navigated to the intravascular treatment site....The material removal element 16 is inserted into the patient's vasculature of the guidewire 42 while in the contracted position illustrated in FIG. 4. (col. 15, lines 36-56)."
>
> To insure delivery of the fluids for infusion or negative pressures for aspiration, the port 82 communicates with a catheter sheath connected to the distal end of the manifold assembly. (col. 11, lines 38-42)

The intrinsic evidence in Ressemann et al.'s specification explicitly describes the guidewire 42 and catheter sheath 90 as separate structures, which provide different functions. Furthermore, Applicants' specification (as shown by the '767 patent which was incorporated by reference) defines the structure and use of a conventional guidewire. Based on such evidence and the plain meaning of the term "guidewire", a person of ordinary skill in the art would not reasonably interpret catheter sheath 90 to be a "guidewire" that is encompassed by the claims of the present invention. Thus, the Examiner's determination that the catheter sheath 90 is a guidewire is not a reasonable interpretation of the term "guidewire." Consequently, claim 1 of

the present invention should be allowable over Ressemann et al. For at least the same reasons, dependent claims 2-19 are also allowable.

Since independent claims 67, and 80 also provide similar structure (e.g., guidewire with a drive shaft in a passage of the guidewire), such independent claims are also allowable over Ressemann et al. For at least the same reasons, dependent claims 68-70 and 72-79 are also allowable over the cited art.

Independent claim 20 provides a guidewire system for passing through an occlusion or stenosis. The system comprises a hollow guidewire having a steerable distal end, a proximal end, and a lumen therebetween. A drive shaft is movably disposed within the hollow guidewire. The drive shaft has a longitudinal axis, a proximal end, and a distal tip portion. A rotating mechanism is coupled to the proximal end of the drive shaft. An actuator is coupled to the drive shaft for controlling the axial movement of the drive shaft. Activation of the actuator advances the drive shaft from a retracted position to an extended position. The rotating distal tip portion in an extended position can create a path through the occlusion or stenosis. Such a guidewire system is not described or suggested by Ressemann et al. Similar to claim 1 (as described above), Ressemann et al. does not show a hollow guidewire with a drive shaft disposed within the hollow guidewire. Moreover, Ressemann et al. does not describe or suggest a steerable guidewire and/or an actuator that controls the axial movement of the drive shaft and that the drive shaft is moveable between a retracted position and an extended position. For at least these reasons, independent claim 20 is also allowable over Ressemann et al. For at least the same reasons, dependent claims 21-30 are also allowable.

Claim Rejections under 35 U.S.C. §103(a)

Claims 75 and 79 are rejected under 35 U.S.C. §103(a) as being unpatentable over Ressemann et al. in view of Noriega. As noted above, Ressemann et al. fails to describe or suggest a drive shaft extending in an axial passable of a hollow guidewire. For at least this reason, dependent claims 75-79 are allowable over Ressemann et al and Noriega.

Dependent Claims

In addition to relying on an allowable independent claim, the dependent claims provide novel aspects that are not described or suggested by the prior art. For example, claims 2, 37, and 70 recite that the guidewire has a diameter between approximately 0.009 inches and 0.035 inches. In contrast, Ressemann et al. specifically states that catheter sheath 90 has an outer diameter of about 0.072". There is no description or suggestion of the claimed diameter range of between 0.009 and 0.035 inches. As is noted in Applicants' specification, the claimed diameter range allows for compatibility with existing interventional cardiology catheters and stent systems, as well as allowing for access to tortuous blood vessels that may not be reached by the larger systems (*See* page 2, lines 27-31 and page 10, lines 13-24 of Applicants application).

Claims 3 and 25 recite that the assembly has a torqueability and pushability to be advanced through a body lumen without the need of a separate guidewire. As noted above, Ressemann et al. explicitly states that the device 10 is an over-the wire construction (col. 7, lines 1-2) in which a guidewire 42 is used to position the material removal element into the patient's vasculature. *See* col. 15, lines 36-65.

Claims 6 and 21 recites that the distal tip is flattened and twisted. Ressemann et al. does not appear to show or describe that the distal tip of the drive shaft is flattened and twisted.

Claim 11 states that the drive shaft may be extended up to 5 centimeters beyond the distal end of the guidewire. Ressemann et al. fails to describe or suggest such a limitation. Ressemann et al. appears to only describe expanding the expandable member 16 and does not appear to describe extending the drive shaft beyond the distal end of the guidewire.

Claim 15 recites that the drive shaft "has riflings which facilitate proximal transportation of a removed occlusive or stenotic material." The Examiner has not explicitly shown where Ressemann et al. illustrates riflings on the drive shaft.

Claim 36 states that the guidewire has a steerable tip. Ressemann et al. does not describe or suggest a steerable tip. As is shown in Figure 15 of the Applicants' application and described on page 10, line 29 to page 11, line 12, the distal end of the guidewire may be

deflected by the user to facilitate advancement through the vascular to the target site. Ressemann et al. does not show or describe such a feature.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

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